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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,281	07/11/2003	Anthony G. Day	GC773-2	4808

7590 08/17/2006

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,281	DAY ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment to page 11 of the specification in the Response filed 6 June 2006 removing an embedded hyperlink has been entered and overcomes the objection of record to the specification, which is WITHDRAWN. Applicant's amendments to claims 1 and 17 remove non-elected invention subject matters of the claimed methods but do not overcome the rejections of record of claims herein, which are restated below.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 17 remain rejected for reasons of record under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed 6 June 2006 have been fully considered but they are not persuasive. Applicant proposes that providing the primary structure, i.e., the amino acid sequence, of a protease the activity of which might be determined with generic assays indicated at, e.g., page 29 of the specification, is adequate to establish a utility for claimed methods of cleaving peptide bond and treating a disease or disorder. As noted in the communication mailed 7 December 2005, a claimed invention must posses a specific, substantial and credible *in vitro* or *in vivo* utility yet the application identifies no specific, substantial, utility for the methods described by claims 1 and 17 known to the inventors at the time the application was filed. The specification discloses no specific "desired protein(s)", and no specific "disease(s) or disorder(s)", and assays discussed at pages 28 and 29 of the specification are entirely generic where the specification fails even to propose any specific set of conditions for an assay. Indeed no particular class of substrates, and no particular classes of diseases or conditions, are identified or

suggested as susceptible to, or targets of, the generic activity of a protease having the amino acid sequence set forth in SEQ ID NO:11. There is no substantial utility where the generic results of the practice of methods of claims 1 and 17 are indistinguishable from the results of methods practiced with any other protease substituted for the protease of SEQ ID NO:11 in these methods. A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Mere allegations of prospective, potential, utility cannot rise to the level of credible assertions of specific *in vitro* and *in vivo* utilities that are substantial. Thus the rejection of record is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 17 also remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph. Applicant's arguments filed 6 June 2006 have been fully considered but they are not persuasive because the claimed invention is not supported by either a **specific** asserted utility or a well established utility for the reasons set forth above, and one skilled in the art clearly would not know how to use the claimed invention in practicing claimed methods. Thus the rejection of record is maintained.

Claims 1 and 17 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 6 June 2006 have been fully considered but they are not persuasive. Applicant proposes that providing the primary structure, i.e., the amino acid

sequence set forth in SEQ ID NO:11 of a protease, an assignment of a generic activity, proteolytic activity, and citations of generic assays for such generic activity is adequate to establish a written description of methods of cleaving peptide bonds and treating diseases or disorders adequate to demonstrate that Applicant was in possession of the claimed methods. But neither the claims nor the specification describe any particular substrate(s) for the protease cleaved, or propose substrate(s) that might be cleaved, in a method of claim 1 or describe or propose any particular disease(s) or disorder(s) that might be treated by using or administering the amino acid sequence of SEQ ID NO:11. There is no convincing evidence that Applicant was in possession of either of the claimed methods at the time the specification was filed where, as noted above, no conditions for an assay and no targets for treatment are suggested by the specification. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification's treatment of the subject matters of claims 1 and 17 requiring a protease comprising the amino acid sequence of SEQ ID NO:11 is considered to be entirely prospective and the rejection of record is therefore maintained.

Claims 1 and 17 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for identification of any particular substrate for the protease comprising the amino acid sequence of SEQ ID NO:11, nor does it reasonably provide enablement for a treating a particular disease or disorder by administering a protease comprising the amino acid sequence of SEQ ID NO:11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the methods of claims 1 and 17 commensurate in scope with these claims.

Applicant's arguments filed 6 June 2006 have been fully considered but they are not persuasive. Applicant suggests that the specification somewhere teaches "how [to] assay SEQ ID NO:11's proteolytic activity" and "what conditions SEQ ID NO:11 . . . may

find use in" provide adequate guidance for experimentation that might eventually lead one of ordinary skill in the art to the practice of the claimed methods "if the art engages in such experimentation". This argument is less than accurate, where the specification provides no guidance as to where to begin to determine what conditions or substrates may be worthwhile for assay of the generic proteolytic activity of the protease of SEQ ID NO:11, nor any guidance as to where to look for diseases or conditions that might be treated with generic proteolytic activity of the protease of SEQ ID NO:11. There is no suggestion of even the "conditions" necessary for practice of a method of claim 1 to determine which "at least one peptide bond" of any peptide or protein might by hydrolyzed by the protease of SEQ ID NO:11. The specification fails to even suggest how the protease of SEQ ID NO:11 might be "administer[ed]" in order to treat an undisclosed "disease or disorder".

It is agreed that 35 U.S.C. § 112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (discussing factors relevant to the analysis of enablement). As to which is the kind of experimentation that is "undue", the standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970). The Federal Circuit approved the standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997), where the lack of guidance necessary

to begin experimentation was the primary factor in invalidating patented claims. Thus the rejection of record is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 17 remain rejected for reasons of record under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 6 June 2006 have been fully considered but they are not persuasive. Applicant argues that a claim cannot be indefinite if "those skilled in the art would understand the scope of the claim when the claim is read in the light of the specification". Claim 1 is therefore indefinite in reciting "a desired protein" because the term "desire" is without dimension or direction and the public and the artisan seeking to establish the metes and bounds of the intended subject matter cannot distinguish, on the basis disclosure of the specification, a "desired" protein from an undesirable protein. Claim 17 is therefore also indefinite in reciting "administering to a patient in need of such treatment" because the term "need" is without dimension or direction and the public and the artisan seeking to establish the metes and bounds of the intended subject matter cannot distinguish, on the basis disclosure of the specification, which patients might "need such treatment" from patients, or persons in general, which need no such treatment where no diseases or conditions that might be treated are identified or suggested. The rejection of record of claims 1 and 17 is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
11 August 2006

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER